3. Making Requests to the Smallpox Vaccine Injury Compensation Program

The U.S. Department of Health and Human Services (HHS) has recently published regulations establishing the Smallpox Vaccine Injury Compensation Program (SVICP). The Program provides medical and lost employment income benefits to members of smallpox emergency response plans who have become injured as a result of receiving smallpox vaccinations.

The Program also provides benefits for individuals who sustained a medical injury from exposure to the virus in the smallpox vaccine through physical contact with a smallpox vaccine recipient or with a person with whom a vaccinated person had contact. There are also death benefits for certain survivors of individuals who died as a direct result of covered injuries resulting from vaccination.

Request Packages for the SVICP, with forms and instructions, are available electronically through the Program's web page, www.hrsa.gov/smallpoxinjury.

Smallpox (Vaccinia) Vaccine Injury Table	
Injury (illness, disability, injury, or condition)	Time interval for first symptom or manifestation of onset of injury after: (1) administration of smallpox (vaccinia) vaccine in recipients (R); or (2) exposure to vaccinia in contacts (C)
1. Significant Local Skin Reaction	R or C: 1-21 days
2. Stevens-Johnson Syndrome	R or C: 1-21 days
3. Inadvertent Inoculation	R or C: 1-21 days
4. Generalized Vaccinia	R or C: 1-21 days
5. Eczema Vaccination	R or C: 1-21 days
6. Progressive Vaccinia	R or C: 1-21 days
7. Postvaccinial Encephalopathy, Encephalitis or Encephalomyelitis	R or C: 1-21 days
8. Fetal Vaccinia	Maternal R or C; any time in gestation until 7 days after birth
9. Secondary Infection	R or C: 1-30 days
10. Anaphylaxis or Anaphylactic Shock	R: 0-4 hours. C: Not Covered.
11. Vaccinial Myocarditis, Pericarditis, or Myopericarditis	R or C: 1-21 days
12. Death resulting from an injury referred to above in which the injury arose within the time interval referred to above (except as specifically provided in specified paragraph of the Table Definition and Requirements).	R or C: No time interval specified

Thank you very much for your cooperation and your valued participation in the smallpox vaccination project. If you have any questions, please do not hesitate to contact the Massachusetts Department of Public Health, Division of Epidemiology and Immunization, at 1-617-983-6800 or 1-888-658-2850.

September 2004

Smallpox Vaccination Adverse Event Clinical Management and Reporting

Guidelines for Health Care Providers

Smallpox vaccination of civilians in Massachusetts is ongoing. We are still in the pre-event planning stage of the smallpox preparedness program, and targeted vaccinees include:

1) Smallpox response teams designated by public health authorities to conduct investigation, follow-up of initial smallpox cases, and disease control; and

2) Health-care teams whose members are trained to provide medical care for initial smallpox patients, should a smallpox event occur.

While all vaccinees will be given a number to call if they have questions or experience vaccine reactions, vaccinees or their household contacts may present in your practice with side effects or adverse events following vaccination.

To monitor the occurrence of adverse events associated with vaccination, both those expected based on previous experience and possible new unexpected adverse events, CDC and state health departments have established the Smallpox Vaccination Adverse Events and Response System. This flyer is intended to help you with:

1) Clinical management of smallpox vaccination adverse events,

2) Reporting of smallpox vaccination adverse events, and

3) Making requests to the Smallpox Vaccine Injury Compensation Program.

Massachusetts Department of Public Health
Division of Epidemiology and Immunization

1. Smallpox Vaccination Adverse Event Clinical Management

Assistance with diagnosis and management of adverse events following smallpox vaccination is available at:

Centers for Disease Control and Prevention (CDC)
CDC Smallpox Vaccine Clinician Information Line
(24 hours/7 days a week) 1-877-554-4625

Massachusetts Department of Public Health (MDPH)
Division of Epidemiology and Immunization
(24 hours/7 days a week) 1-617-983-6800 or toll free at 1-888-658-2850

CDC. Smallpox Vaccination and Adverse Reactions: Guidance for Clinicians. MMWR 2003:52(RR-04);1-28. Available at www.cdc.gov/mmwr/preview/mmwrhtml/rr5204a1.htm

CDC. Notice to Readers: Smallpox Vaccine Adverse Events Monitoring and Response System for the First Stage of the Smallpox Vaccination Program. MMWR 2003:52(05);88-89, 99. Available at www.cdc.gov/mmwr/preview/mmwrhtml/mm5205a5.htm

CDC. Update: Cardiac-Related Events During the Civilian Smallpox Vaccination Program - United States, 2003. MMWR 2003:52;492-496.

Clinical Evaluation Tools for Smallpox Vaccine Adverse Reactions are available on line at: www.bt.cdc.gov/agent/smallpox/vaccination/clineval. These tools will assist you with triage and management of smallpox vaccine adverse events except cardiac events (see below). They are color-coded and include algorithms for diagnosing and managing the following adverse events:

- Dermatologic reactions/Localized to vaccination site;
- Dermatologic reactions/Nontoxic appearance, distant from vaccination site (or in a close contact);
- Dermatologic reactions/Toxic appearance, distant from vaccination site (or in a close contact);
- Ophthalmologic reactions/Inadvertent inoculation, vaccinee (or in a close contact);
- Ophthalmologic reactions/Eye splash or other potential exposure to vaccinia virus, vaccinee (or in a close contact);
- Neurologic reactions, vaccinee (or in a close contact);
- Use of intravenous Vaccinia Immune Globulin (VIG) (first line agent), vaccinee (or in a close contact).

Guidelines for using these tools are included with this flyer.

For guidance regarding triage and management of cardiac events following smallpox vaccination, please consult: CDC. Update: Cardiac-Related Events During the Civilian Smallpox Vaccination Program - United States, 2003. MMWR 2003:52;492-496. URL: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5221a2.htm

If you need medical consultation regarding any smallpox vaccination adverse event, or if you need assistance in obtaining Investigational New Drug (IND) therapies Vaccinia Immune Globulin (VIG) (first line agent) or Cidofovir (second line agent) for potential smallpox vaccine adverse events, please contact MDPH at 1-617-983-6800 or toll free at 1-888-658-2850. Please note that IND therapies can only be released through MDPH.

2. Smallpox Vaccination Adverse Event Reporting

Step One: Report all smallpox vaccination adverse events to the following number:

MDPH Division of Epidemiology and Immunization
(24 hours/7 days a week), 1-617-983-6800 or toll free at 1-888-658-2850

Step Two: Complete an electronic Vaccine Adverse Event Reporting System (VAERS) form on-line at www.vaers.org. MDPH staff members are available to help you complete the VAERS form. If you do not have internet access, an MDPH staff member will complete the VAERS form for you over the telephone. Upon submission of the report, you will be notified of your report's unique VAERS electronic report (E-Report) number.

Step Three: Print a copy of the electronic VAERS form. The system will prompt you to print after submission: "Print E-Report and Confirmation for Your Records".

Step Four: Fax a copy of the completed VAERS form to MDPH as soon as possible. Please remember to include the patient's Personal Vaccination Number (PVN) and VAERS E-Report number on the cover sheet.

MDPH confidential fax number: 1-617-983-6813, attention "VAERS Coordinator"

Timeliness of Smallpox Vaccination Adverse Event Reporting

MDPH recommends that all smallpox adverse events be reported electronically. Reports submitted in this manner will be available to the CDC as data within as little as 24 hours, whereas paper based reports would not be available as data for up to two weeks. If it is impossible for you to work with MDPH to submit an electronic VAERS form, then you can phone VAERS to obtain a form (1-800-822-7967) and return the form to VAERS by fax (1-877-721-0366) or by mail (P.O. Box 1100, Rockville, MD, 20849-1100).

Report Immediately

Serious or unexpected adverse events which require CDC consultation or IND therapies (VIG or cidofovir)

Report Within 48 Hours of Recognition

Other serious adverse events, which include but are not limited to:

- Inadvertent inoculation
- Eczema vaccinatum
- Erythema multiforme major or Stevens-Johnson syndrome
- Fetal vaccinia
- Generalized vaccinia
- Ocular vaccinia
- Post-vaccinial encephalitis or encephalomyelitis
- Progressive vaccinia
- Pyogenic infection of vaccination site
- Vaccinia transmission to contacts
- Vaccination of persons with a contraindication to vaccination
- Vaccinial myocarditis, pericarditis,or myopericarditis
- Adverse events resulting in hospitalization, permanent disability, life-threatening illness, or death

Report Within 7 Days of Recognition

- Non-serious adverse events
- Any adverse event that is of concern to you or the patient